Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., and JAZZ PHARMACEUTICALS IRELAND LIMITED,	**Civil Action No. 13-0391 (ES) (JAD)**
Plaintiffs,	**OPINION**
v.	
AMNEAL PHARMACEUTICALS, LLC, et al.,	
Defendants.	

SALAS, DISTRICT JUDGE

Before the Court is the parties' request for claim construction. The Court held a *Markman* hearing on April 27, 2017. (D.E. No. 350). This Opinion sets forth the Court's constructions of the disputed terms.

I. Background[1]

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (together, "Jazz") market the drug product XYREM®, which is used to treat patients with two of the most prevalent symptoms of narcolepsy: excessive daytime sleepiness and cataplexy. Defendants[2] filed Abbreviated New Drug Applications with the FDA seeking approval to market generic versions of XYREM®. Jazz sued Defendants for patent infringement under 35 U.S.C. § 100 *et seq.*, alleging,

[1] The Court draws these facts from the parties' briefing and provides this background for contextual purposes only. Nothing in this section should be construed as a finding of fact by this Court.

[2] The Defendants in this case are Amneal Pharmaceuticals, LLC ("Amneal"); Lupin Limited; Lupin Pharmaceuticals, Inc., Lupin Inc. (collectively, "Lupin"); Watson Laboratories, Inc. ("Watson"); and Par Pharmaceutical, Inc. ("Par"). Par did not participate in this *Markman* proceeding. (*See* D.E. No. 321 at 1 n.1; D.E. No. 315 at 2 n.1).

among other things, that Defendants' proposed generic versions of XYREM® will infringe Jazz's patents.

XYREM® is sold as a concentrated oral solution that is diluted by the patient with water prior to its use at bedtime. The active ingredient in XYREM® is sodium oxybate (also known as gamma-hydroxybutyrate, or GHB). Under certain conditions, GHB may become chemically unstable and break down. GHB solutions may also become prone to microbial contamination.

This *Markman* decision involves eleven patents stemming from two patent families: the '431 patent family and the '306 patent family.[3] The '431 patent family covers pharmaceutical compositions of GHB—and methods of making and using such pharmaceutical compositions—that are chemically stable and microbial resistant, without the need for a preservative.

The '306 patent family (comprising what are known as "DDI"—or "drug-drug-interaction"—patents) covers specific methods of treating sleep disorders in patients receiving both GHB and valproate. Valproate (also known as divalproex sodium) is used as an anticonvulsant and mood-stabilizing drug, primarily for treating epilepsy and bipolar disorder. Significantly, valproate is involved in processes that can both raise and lower the levels of GHB in a patient. So, the DDI patents claim methods for safely co-administering GHB and valproate to treat patients with sleep disorders.

The parties submitted a Joint Claim Construction and Prehearing Statement identifying seven disputed terms. (D.E. No. 315 ("Joint Stmt.")). Following *Markman* briefing,[4] the parties

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[3] The '431 patent family comprises 9 patents: U.S. Patent Nos. 6,472,431 ("the '431 patent"); 6,780,889 ("the '889 patent"); 7,262,219 ("the '219 patent"); 7,851,506 ("the '506 patent"); 8,263,650 ("the '650 patent"); 8,461,203 ("the '203 patent"); 8,324,275 ("the '275 patent"); 8,859,619 ("the '619 patent"); and 8,952,062 ("the '062 patent").

The '306 patent family comprises 2 patents: U.S. Patent Nos. 8,772,306 ("the '306 patent") and 9,050,302 ("the '302 patent").

[4] (*See* D.E. No. 321 ("Jazz Open. Br."); D.E. No. 323 ("Def. Open. Br."); D.E. No. 333 ("Def. Resp. Br."); & D.E. No. 334 ("Jazz Resp. Br.")).

submitted an Amended Joint Claim Construction and Prehearing Statement reducing the number of disputed terms to five. (D.E. No. 348 ("Am. Joint Stmt.")).

II. Legal Standard

A. Basics of Claim Construction

A patent claim is that "portion of the patent document that defines the scope of the patentee's rights." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 835 (2015).[5] When the parties in a patent infringement action "present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

The words of a claim are generally given their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art [(a "POSA")] in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). To determine the ordinary and customary meaning of a disputed term, the court must look to "those sources available to the public that show what a [POSA] would have understood [the] disputed claim language to mean." *Id.* at 1314.

B. Intrinsic and Extrinsic Evidence

"In determining the proper construction of a claim, the court has numerous sources that it may properly utilize for guidance. These sources . . . include both intrinsic evidence (e.g., the patent specification and file history) and extrinsic evidence (e.g., expert testimony)." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

[5] Unless otherwise indicated, all internal citations and quotation marks are omitted, and all emphasis is added.

With respect to intrinsic evidence, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. Indeed, "the context in which a term is used in the asserted claim can be highly instructive." *Id.* Similarly, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.*

Importantly, the specification "is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics*, 90 F.3d at 1582). "[T]he specification may reveal a special definition given to a claim term by the patentee" or "may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1316. Thus, "the specification necessarily informs the proper construction of the claims," and it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1316-17. Notably, however, the court may "not read limitations from the specification into claims." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). In particular, the Federal Circuit has "repeatedly warned against confining the claims to . . . embodiments" described in the specification. *Phillips*, 415 F.3d at 1323.

The court must also consider the patent's prosecution history, i.e., "the complete record of the proceedings before the PTO . . . includ[ing] the prior art cited during the examination of the patent." *Id.* at 1317. Although the prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes," it can nevertheless "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

The court may also rely on extrinsic evidence, i.e., "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id*. But, extrinsic evidence "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319.

C. Indefiniteness at the *Markman* Stage

Patent claims must "inform those skilled in the art about the scope of the invention with reasonable certainty," when read in light of the specification and prosecution history. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A patent claim that fails to so inform a POSA is indefinite. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1340-41 (Fed. Cir. 2015). "A party challenging the validity of a patent must establish invalidity by clear and convincing evidence." *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1294 (Fed. Cir. 2015) (citing *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011)). "Of course, claims are not indefinite merely because they present a difficult task of claim construction." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008). Rather, "if the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree," the claim is sufficiently clear to avoid invalidity on indefiniteness grounds. *See id.*

Claim indefiniteness presents a question of law, and district courts may find claims indefinite at the *Markman* stage. *See, e.g.*, *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1368-74 (Fed. Cir. 2014) (affirming the district court's indefiniteness ruling at claim construction post-*Nautilus*); *Mycone Dental Supply Co. v. Creative Nail Design, Inc.*, No. 11-4380, 2014 WL

3362364, at *4 (D.N.J. July 9, 2014) ("[I]ndefiniteness is a significant issue to be adjudicated at claim construction . . . .").[6]

III. Construction of Disputed Claim Terms

A. The '431 Patent Family

1. "Third Container Means"

Claim 17 of the '650 patent: "The set of claim 15, comprising a *third container means* capable of retaining a first container means, a second container means, and one or more delivery vehicles capable of administering the pharmaceutical composition to the patient."[7]

Jazz	Defendants	The Court
"a container distinct from a first and second container"	This is a means-plus-function term under 35 U.S.C. § 112 ¶ 6; and it is indefinite.	This is a means-plus-function term under 35 U.S.C. § 112 ¶ 6; and it is indefinite.

i. "Third Container Means" is a Means-Plus-Function Limitation

As a threshold matter, the parties dispute whether "third container means" is a means-plus-function limitation. "A means-plus-function limitation recites a function to be performed rather than definite structure or materials for performing that function." *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308, 1318 (Fed. Cir. 2003). The relevant statutory language provides that

> [a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, materials, or acts described in the specification and equivalents thereof.

[6] To be sure, courts often "decline to address indefiniteness arguments in claim construction because they are potentially dispositive, require a high burden of proof, and may more profitably be considered in connection with patent validity. *Fresenius Kabi USA, LLC v. Fera Pharms, LLC*, No. 15-3654, 2016 WL 5109142, at *9 (D.N.J. Sept. 20, 2016) (collecting cases); *see also Int'l Dev. LLC v. Richmond*, No. 09-2495, 2010 WL 4703779, at *7 (D.N.J. Nov. 12, 2010) ("It may be true that determining indefiniteness of claim language is a question of law that is drawn from the court's performance of its duty as the construer of patent claims, which is the same duty that gives rise to the *Markman* hearing . . . . However, this does not outweigh the practical considerations that militate against determining indefiniteness prior to the end of all discovery.").

[7] "Third container means" also appears in claim 18 of the '650 patent and claim 16 of the '619 patent.

35 U.S.C. § 112, ¶ 6.[8]

Use of the word "means" in claim language creates a presumption that § 112, ¶ 6 applies. *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259 (Fed. Cir. 2008). This presumption, however, can be rebutted in two ways. *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427 (Fed. Cir. 1997). First, "where a claim uses the word 'means,' but specifies no function for the 'means,' it does not implicate section 112." *Id.* Second, "where a claim recites a function, but then goes on to elaborate sufficient structure, material, or acts within the claim itself to perform entirely the recited function, the claim is not in means-plus-function format." *Id.* at 1427-28. The second scenario applies here.

The Federal Circuit has explained that "[s]ufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure." *TriMed, Inc.*, 514 F.3d at 1259-60. Courts "decide on an element-by-element basis, based upon the patent and its prosecution history, whether § 112, ¶ 6 applies." *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996).

Jazz argues that "third container means" is not a means-plus-function limitation because the claims containing that term recite sufficient structure. (Jazz Open. Br. at 5-8; Jazz Resp. Br. at 6-9). Specifically, Jazz contends that the claims "describe[] a structure—a container—that is used to hold other structures such as a first and second container and delivery vehicles." (Jazz Open. Br. at 8). According to Jazz, "Defendants recognize that the terms 'first container means' and 'second container means' recite sufficient structure because Defendants do not contend that these terms fall under § 112, ¶ 6." (*Id.*). And Jazz asserts that the claims' functional description

[8] The applicable pre-AIA statute—35 U.S.C. § 112, ¶ 6—is identical to current 35 U.S.C. § 112(f).

for "third container means"—i.e., that the "third container means" is "capable of" performing a function—does not convert the term into a means-plus-function limitation. (*Id.*).

Defendants counter that, as an initial matter, "third container means" is presumed to be a means-plus-function limitation because the claim contains the word "means." (Def. Open. Br. at 13; Def. Resp. Br. at 8). Defendants then argue that there is no evidence to rebut this presumption, as the "claims plainly recite three functions for the 'third container means' and do not describe any contemplated structure to perform those functions." (Def. Open. Br. at 13). In fact, according to Defendants, "there is no explicit structure *at all* recited for the 'third container means.'" (*Id.* at 14) (emphasis in original). Rather, Defendants argue that "the word 'container' conveys the general function of containing, not a specific structure." (*Id.* at 15). Defendants further argue that "even if 'container' could reasonably refer to some endless category of structures, it is far from sufficient to rebut the means-plus-function presumption here." (*Id.*). This is especially true, Defendants submit, where "the *same* modifier is used for the distinct 'first' and 'second' means as well." (Def. Resp. Br. at 9) (emphasis in original).

The Court concludes that "third container means" is a means-plus-function limitation. At the outset, the Court presumes that "third container means" invokes § 112, ¶ 6. This is because the claims containing "third container means" use the term "means" to describe a limitation: "capable of retaining a first container means, a second container means, and one or more delivery vehicles." *See Biomedino, LLC v. Waters Tech. Corp.*, 490 F.3d 946, 950 (Fed. Cir. 2007). To be sure, this presumption applies even though the claims recite "means" and not "means for." *See, e.g., id.* ("When a claim uses the term 'means' to describe a limitation, a presumption inheres that the inventor used the term to invoke § 112, ¶ 6."); *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363,

1375 (Fed. Cir. 2003) (same); *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998) (same).

Next, to determine if this presumption is rebutted, the Court must assess whether the claims specify the "exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure." *TriMed*, 514 F.3d at 1259-60. If the claims recite sufficient structure, then the presumption falls and the term does not invoke § 112, ¶ 6. *See id.* Here, Jazz argues that "container" constitutes sufficient structure to rebut the means-plus-function presumption. (Jazz Open. Br. at 5-8; Jazz Resp. Br. at 6-9). The Court disagrees.

To start, the Court must look to the claims themselves to assess whether they recite sufficient structure. So, what do the claims say about "third container means"? Only that it must be capable of retaining a "first container means," a "second container means," and "one or more delivery vehicles." In other words, to the extent "container" refers to structure, the "third container means" is "the only recitation of structure with the remainder [of the claim] pertaining solely to the function of the means limitation." *See Unidynamics Corp. v. Automatic Prods. Int'l., Ltd.*, 157 F.3d 1311, 1319 (Fed. Cir. 1998).

For instance, the claims do not recite any information about how big the "third container means" must be to carry out its functions, or what materials must comprise the "third container means" so that it can carry out its functions. *Cf. Cole*, 102 F.3d at 531 ("An element with *such a detailed recitation of its structure, as opposed to its function*, cannot meet the requirements of the statute."). And the other claimed items ("first container means," "second container means," and "one or more delivery vehicles") do not inform anything about the "third container means" because they, too, have no description in the claims; one must consult the specification to learn what those

containers are. Thus, a POSA would not know, without consulting at least the specification, what kind of container could or could not carry out the claimed functions. *See TriMed*, 514 F.3d at 1259-60. Accordingly, the presumption that "third container means" invokes § 112, ¶ 6 stands. *See id.*

The absence of a detailed and specific structure distinguishes "third container means" from two cases Jazz cites. (*See, e.g.*, Jazz Open. Br. at 8). The first case, *Cole*, involved a patent for disposable briefs used during toilet training. 103 F.3d at 526. Among other features, the briefs contained separate absorbent layers that could easily be torn open and thrown away. *Id.* On appeal, the Federal Circuit considered whether the term "perforation means" invoked § 112, ¶ 6. *Id.* at 530. Claim 1 in relevant part stated: "*perforation means extending from the leg band means to the waist band means through the outer impermeable layer means for tearing the outer impermeable layer means for removing the training brief in case of an accident by the user*." *Id.* at 530. The Federal Circuit found that the claim recited sufficient structure to rebut the means-plus-function presumption. *Id.* at 531. In doing so, the Federal Circuit relied on the claims' detailed description of the structure, reasoning that "[t]he claim describes not only the structure that supports the tearing function, but also its location (extending from the leg band to the waist band) and extent (extending through the outer impermeable layer)." *Id.* The Federal Circuit concluded: "[a]n element with *such a detailed recitation of its structure, as opposed to its function*, cannot meet the requirements of the statute." *Id.*

The second case, *Envirco Corp. v. Clestra Cleanroom, Inc.*, involved a patent for a centrifugal fan and filter assembly for clean-room environments. 209 F.3d 1360, 1361 (Fed. Cir. 2000). At issue during claim construction was the term "second baffle means." Claim 1 stated in relevant part:

> second baffle means disposed radially outwardly of said centrifugal fan means and said first baffle means, said second baffle means having inner surfaces for directing the airflow from said centrifugal fan means inwardly of said primary housing and between said first baffle means and said filter means whereby air being introduced into said housing by said centrifugal fan means will be directed radially outwardly of said centrifugal fan means and guided by said first baffle means towards said second baffle means and thereafter by said second baffle means between said first baffle means and said air filter means.

Id. at 1363. The district court construed "second baffle means" as a means-plus-function limitation. *Id.* On appeal, the Federal Circuit reversed, holding that "second baffle means" was not a means-plus-function limitation because the claim recited sufficient structure for performing the claimed function. *Id.* at 1364-65. The court observed that the term "baffle" itself is a structural term and that the "dictionary definition of the word 'baffle' is a device (as a plate, wall or screen) to deflect, check, or regulate flow." *Id.* at 1365 (citing *Webster's Ninth New Collegiate Dictionary* 124 (1990)).

But the Federal Circuit did not stop there. It also relied on the claims' detailed recitation of "second baffle means." In the very next sentence, the Federal Circuit explained that

> the claims describe the particular structure of this particular baffle ("having inner surfaces for directing airflow . . . radially outward . . . and thereafter . . . between said first baffle means and said air filter means"). This recital of structure conflicts with the statutory requirement that means-plus-function claim elements state a function "without the recital of structure."

Id. (quoting 35 U.S.C. § 112, ¶ 6). Indeed, the Federal Circuit concluded that "the second baffle limitation is not a means-plus-function claim element" because "the claims recite sufficient structure, *including details about the location and formational details about the second baffle*." *Id.* Here, the claims do not recite anything about "third container means" other than what it must be capable of doing. Consequently, a POSA would "need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure." *TriMed,* 514 F.3d at 1260.

Jazz also relies on *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996). (Jazz Open. Br. at 8). In that case, the Federal Circuit called the term "container" a "commonplace structural term[]." As Defendants correctly point out, however, the claim term at issue in *Greenberg* did not recite "means" and was thus governed by the opposite presumption: that means-plus-function requirements did not apply. (Def. Resp. Br. at 8-9 n.4); *see Advanced Ground Info. Sys., Inc. v. Life360, Inc.*, 830 F.3d 1341, 1347 (Fed. Cir. 2016) ("The failure to use the word 'means' also creates a rebuttable presumption . . . that § 112, para. 6 does not apply."). And as discussed above, even if "container" is itself a structural term, the claims lack sufficient information about "third container means" for a POSA to know, without consulting the specification, what kind of container can perform the claimed functions.

ii. "Third Container Means" is Indefinite

Because the Court finds that "third container means" is a means-plus-function limitation, it must engage in a two-step process to construe the term. *Asyst Techs., Inc. v. Empak, Inc.*, 268 F.3d 1364, 1369 (Fed. Cir. 2001). The first step "is to identify the function explicitly recited in the claim." *Id.* The second step "is to identify the corresponding structure set forth in the written description that performs the particular function set forth in the claim." *Id.* "Under this second step, structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003). "If the patentee fails to disclose adequate corresponding structure, the claim is indefinite." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1352 (Fed. Cir. 2015); *see also EON Corp. IP Holdings, LLC v. AT&T Mobility LLC*, 785 F.3d 616, 621 (Fed. Cir. 2015) ("Means-plus-function claim limitations under § 112, ¶ 6 must satisfy the definiteness requirement of § 112, ¶ 2.").

First, the Court must identify the functions "third container means" performs. As noted above, those functions are "retaining a first container means, a second container means, and one or more delivery vehicles capable of administering the pharmaceutical composition to the patient."

Second, the Court must determine whether the specification discloses sufficient structure that corresponds to the claimed functions. *Williamson*, 792 F.3d at 1351. Where there are multiple claimed functions, "the patentee must disclose adequate corresponding structure to perform all of the claimed functions." *Id.* at 1351-52.

Jazz argues that the specification "describes various container means." (Jazz Open. Br. at 9) (citing '650 patent at col. 16, l. 1-38). And according to Jazz, the specification "provides a structure for the third container means"—a container. (*Id.*) (citing '650 patent at col. 10, l. 3-6 and col. 16, l. 2-7). In particular, Jazz asserts that the "third container means" can be an injection or blow-molded plastic container. (*Id.*) (citing '650 patent at col. 16, l. 29-32). Jazz also asserts that the "third container means" could be other "structures explicitly listed" in the specification, such as a bottle or flask. (Jazz. Resp. Br. at 10). Jazz further contends that the specification includes "other suitable storage means" that are "able to retain the structures recited in the claims." (*Id.*).

Defendants first argue that "the specification and prosecution history lack *any* corresponding structure clearly linked to the claimed "third container means." (Def. Open. Br. at 16) (emphasis in original). Defendants note that the specification "not once mentions explicitly a 'third container means' of the invention." (*Id.*). While Defendants acknowledge that the specification refers generally to "container means," they assert that the specification does so either "in terms of pure function" or by listing "structures not tied in any way to the claimed '*third* container means' or its functions." (*Id.* at 16-17) (emphasis in original). Rather, Defendants contend that those structures are tied "to the first or second container means or delivery vehicle

elements." (*Id.* at 17) (citing '650 patent at col. 16, l. 12-14 ("the container means may itself be a syringe, pipette, vial, ampule or other such like apparatus"); *id.* at col. 16, l. 22-25 ("The container means will generally include at least one vial, test tube, flask, bottle, pouch syringe or other container means."); *id.* at col. 16, l. 35-36 ("Such an instrument may be a drinking cup, syringe, pipette, or any such medically approved delivery vehicle.")). According to Defendants, "[n]o one would confuse these disclosed structures (*e.g.*, syringe, pipette, vial) as corresponding to the claimed 'third container means.'" (Def. Open. Br. at 17). Alternatively, Defendants argue that, to the extent the specification adequately links structure to "third container means," "there is no structure disclosed to achieve all three functions of 'retaining' the first and second container means as well as one or more delivery vehicles." (*Id.*).

The Court concludes that the specification lacks a corresponding structure for "third container means." First, the Court agrees with Defendants that the specification does not explicitly link any structure to "third container means." Jazz does not point the Court to any explicit reference in the specification to a "third container means" of the invention.

The Court also concludes that the specification does not implicitly link any structure to "third container means." Jazz's argument that the "third container means" can be a container is unavailing because, under Federal Circuit law, the specification must identify the *particular* structure that is used to carry out the claimed function. *See Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1385 (Fed. Cir. 2009) ("That ordinarily skilled artisans could carry out the recited function in a variety of ways is precisely why claims written in 'means-plus-function' form must disclose the particular structure that is used to perform the recited function."). In other words, a "patentee cannot avoid providing specificity as to structure simply because someone of ordinary skill in the art would be able to devise a means to perform the claimed function." *Id.*

Although Jazz argues that the "third container means" could be "injection or blow-molded plastic containers," the specification suggests that those containers perform one function: "containing the vials in close confinement for commercial sale." *See* '650 patent at col. 16, l. 28-31. The specification does not say anything about those containers retaining a "first container means," a "second container means," and "one or more delivery vehicles"—functions the "third container means" must be capable of doing. *See Media Rights Techs., Inc.*, 800 F.3d at 1374-75 (finding the means-plus-function term "compliance mechanism" indefinite because the specification did not recite any specific structure to perform all four claimed functions). The same is true for the other structures listed in the specification, such as a bottle or flask. Accordingly, the term "third container means" is indefinite under § 112, ¶ 2, and the claims reciting that term (claims 17 and 18 in the '650 patent and claim 16 in the '619 patent) are invalid. *See Biomedino*, 490 F.3d at 950 ("If there is no structure in the specification corresponding to the means-plus-function limitation in the claims, the claims will be found invalid as indefinite.").

2. "the components are admixed sequentially" & "the components are admixed simultaneously"[9]

Claim 1 of the '203 patent: "A method of rendering an aqueous medium resistant to microbial growth, said method comprising admixing a salt of gamma hydroxybutyrate with the aqueous medium, adjusting the concentration of the gamma-hydroxybutyrate salt in the aqueous medium to a final concentration of from about 310 to about 750 mg/ml, and adjusting the pH of the medium to a final pH of about 6 to about 9, so that the medium is chemically stable and resistant to microbial growth, wherein the medium would not need to contain a preservative."

Claim 7: "The method of claim 1, wherein *the components are admixed sequentially*."

Claim 8: "The method of claim 1, wherein *the components are admixed simultaneously*."

[9] The Court will refer to these terms as the "admixed" terms. For clarity, the parties appear to agree that the plain and ordinary meaning of "admix" is "adding and mixing." (*See* April 27, 2017 *Markman* Transcript ("Tr.") at 82:9-10; 91:5-7).

Phrase	Jazz	Defendants	The Court
"the components are admixed sequentially"	No construction necessary	Indefinite, but to the extent it may be construed: "the act of creating a mixture by adding components in succession without others coming in between"	No construction necessary
"the components are admixed simultaneously"	No construction necessary	Indefinite, but to the extent it may be construed: "the act of creating a mixture by adding components at the same time"	No construction necessary

Jazz argues that the "admixed" terms require no construction. (Jazz Open. Br. at 11-12; Jazz Resp. Br. at 2-6). According to Jazz, a POSA "would readily understand the components of claim 1 that were to be admixed. Claim 1 requires admixing a salt of GHB, an aqueous medium and a pH adjusting agent, which adjusts the pH of the medium to a final pH of about 6 to about 9." (Jazz Open. Br. at 12).[10] Jazz also notes that the "components" in claim 1 could include the GHB salt's reactants (GBL and NaOH), since "the GHB salt does not have to be pre-formed and can be

[10] This statement suggests that Jazz believes a pH-adjusting agent is a required component in claim 1. But in Jazz's Responsive *Markman* Brief, Jazz states that a pH adjusting agent "*can* also be a component" in claim 1. (Jazz Resp. Br. at 3 n.2; *see also id.* (stating that a "pH adjusting agent *could* be used" in claim 1)). At the *Markman* hearing, the Court raised this inconsistency and asked Jazz whether claim 1 requires a pH-adjusting agent. (*See* Tr. at 73:14-77:4). Following some back and forth with the Court, Jazz stated that the "requirements of [claim 1] is it has to be 6 to 9, pH, it is not there has to be a pH adjusting agents [sic]." (*Id.* at 75:24-76:1). When the Court asked Jazz how "one adjust[s] the pH," Jazz responded, "[a] couple ways, but it requires an element." (*Id.* at 76:21-24). And when the Court asked Jazz if that meant that pH adjustment "requires an additional component," Jazz responded: "Yes." (*Id.* at 76:25-77:2). Jazz also stated that claim 1 requires adjusting the pH. (*Id.* at 76:19-20 ("[Claim 1] requires, I am not trying to quibble. It requires adjusting the pH. Yes.")). So, Jazz appears to have settled on the position that claim 1 requires at least three components: GHB, an aqueous medium, and a component for adjusting the pH.

admixed as its reactants." (Jazz Resp. Br. at 4). This scenario "provides more than two components combined with the aqueous medium." (*Id.*).

Jazz also explains how a POSA would understand the terms "sequential" and "simultaneous" in this context:

> Sequential admixing of the components would require, for example, first admixing GHB and an aqueous medium, and then separately admixing a pH adjusting agent with the previously admixed GHB and aqueous medium. Simultaneous admixing of the components, on the other hand, would require admixing GHB, an aqueous medium, and a pH-adjusting agent all at the same time.

(Jazz Open Br. at 12).

Defendants argue that the "admixed" terms are indefinite under 35 U.S.C. § 112, ¶ 2. (Def. Open. Br. at 6-10; Def. Resp. Br. at 1-4). First, Defendants contend that a POSA would not understand "what is meant by the 'components' to be 'admixed' because the term 'components' is not defined and does not have antecedent basis in independent claim 1 from which claims 7 and 8 both depend." (Def. Open. Br. at 6). Second, Defendants maintain that only two ingredients are "admixed" in claim 1: GHB salt and the aqueous medium. (*Id.*). And according to Defendants, it is impossible to admix two ingredients sequentially; rather, two ingredients are necessarily admixed simultaneously.[11] (*Id.*). Consequently, claim 8 "has no further differentiation from claim 1 and fails to further shine light on what is meant by 'components.'" (*Id.*).[12] Following this logic,

[11] Specifically, Defendants argue that "[a]dmixing only two components cannot be done sequentially since there is only one event—ingredient A added to ingredient B and mixed. A sequence means that there must be at least an additional event, e.g., a third ingredient C." (*Id.* at 9) (footnote omitted).

[12] As a general matter, the doctrine of claim differentiation "creates a presumption that each claim in a patent has a different scope. The difference in meaning and scope between claims is presumed to be significant to the extent that the absence of such difference in meaning and scope would make a claim superfluous." *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1351 (Fed. Cir. 2005). The Federal Circuit has cautioned, however, "that claim differentiation is a guide, not a rigid rule." *Curiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1381 (Fed. Cir. 2006).

Defendants argue that claims 7 and 8 must include more than two ingredients,[13] but a POSA would not be able to discern what the additional ingredient is (or ingredients are). (*Id.*). Defendants submitted inventor testimony to support their argument that "admixing does not happen until more than one so-called 'component' is added and mixed with another." (*Id.* at 8-9; *see also* D.E. Nos. 321-1 & 321-2).

Alternatively, Defendants ask the Court to adopt their proposed constructions of the "admixed" terms, which Defendants say are consistent with the terms' plain and ordinary meaning. (Def. Open. Br. at 10-12; Def. Resp. Br. at 4-6). Defendants' proposed constructions are primarily based on dictionary definitions, as Defendants contend that "neither the claims nor the specification of the '203 patent provide further guidance as to what is meant by" sequential or simultaneous admixing. (Def. Open. Br. at 11). Defendants submit that the plain and ordinary meaning of "sequential" is "following in sequence." (*Id.*) (citing Ninth New Collegiate Dictionary – Merriam Webster (1988) ("Webster's Ninth") at 1074). And, according to Defendants, "a 'sequence' is understood to be 'a continuous or connected series.'" (*Id.*) (citing Webster's Ninth at 1073; *Janssen, L.P. v. Barr Labs., Inc.*, Nos. 07-1515, 07-5982, 08-3012, 08-2892, 2009 WL 424389, at *4 (D.N.J. Feb, 19, 2009)). Thus, Defendants argue that, "[i]n order for there to be any meaningful 'series' as to the adding of components as alleged in claim 7 of the '203 patent, there must be no other event (i.e., packaging, flavoring) that comes in between the alleged sequential admixing of components, whatever those components are." (*Id.*).

Similarly, Defendants submit that the plain and ordinary meaning of "simultaneous" is "existing or occurring at the same time." (*Id.* at 12) (citing Webster's Ninth at 1099; *Janssen,*

[13] Here's why: claim 7 must include more than two ingredients because sequential admixing necessarily requires at least three ingredients, and claim 8 must include more than two ingredients because, under the doctrine of claim differentiation, claim 8 must be different than claim 1. (*See id.* at 6-7).

2009 WL 424389, at *4). Thus, Defendants argue that, "in order to add the components as alleged in claim 8 of the '203 patent simultaneously, whatever those components are, they must be added at the same time." (*Id.*).

In response to Defendants' proposed constructions, Jazz argues that Defendants "seek to read several limitations into the claims." (Jazz Resp. Br. at 5). One such limitation, according to Jazz, is Defendants' phrase, "the act of creating a mixture." (*Id.*). Jazz submits that "there is nothing in the intrinsic record that requires adding and mixing components to result in 'creating a mixture.'" (*Id.* at 5-6). Jazz further contends that, "to the extent a mixture is required, then construing 'admixed' to include 'the act of creating a mixture' would be an unnecessary 'exercise in redundancy.'" (*Id.* at 6) (citing *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997)).

Jazz also challenges Defendants' proposed construction of "sequentially." (*Id.*). Jazz argues that Defendants base their argument on a dictionary definition for "sequence," which provides that a sequence can either be continuous or connected. (*Id.*). But "[n]either 'continuous,' nor 'connected' . . . requires actions with no intervening steps." (*Id.*). Jazz notes that "Defendants do not cite any authority or dictionary to the contrary for those two words." (*Id.*).

The Court agrees with Jazz that the "admixed" terms require no construction. In light of the claim language and the specification, a POSA would know that "components" refers to at least a salt of GHB and an aqueous medium. *See, e.g.*, Claim 1 of '203 patent. To the extent a pH-adjusting agent is used in claim 1, "components" refers to that, too. *See, e.g.*, '203 patent at col. 6, l. 37-39 (noting that the "pharmaceutical composition may comprise a pH adjusting or buffering agent"). Jazz also notes that the GHB salt does not have to be pre-formed, but instead can be admixed as its reactants (GBL and NaOH). (Jazz Resp. Br. at 4). In this scenario, the GHB salt's

reactants are "components" for purposes of claims 7 and 8. Based on the foregoing, the Court concludes that claim 1 is not limited to only two components, but instead may comprise at least three components. And a POSA would not have difficulty discerning what those components are in view of the patent specification and claim language.

The Court also concludes that a POSA would understand what it means to admix the components simultaneously or sequentially. These are common, non-technical terms that, in light of the claim language and specification, do not require construction. *See U.S. Surgical Corp.*, 103 F.3d at 1568 (observing that claim construction "is not an obligatory exercise in redundancy"). To be sure, Defendants argue that claim 7 requires at least three components because a POSA cannot, as a practical matter, admix two components sequentially. (Def. Open. Br. at 6). While that may be true, the Court need not resolve that issue because claim 1 can encompass more than two components (e.g., a GHB salt, an aqueous medium, and a pH-adjusting agent). Therefore, it may be the case that a POSA can practice claim 7 only when claim 1 encompasses at least three components. *See Kruse Tech. P'ship v. Volkswagen AG*, 544 F. App'x 943, 951 (Fed. Cir. 2013) ("This court's precedent is clear that a claim need not cover every disclosed embodiment.").

Accordingly, the Court concludes that the "admixed" terms require no construction. The Court will reject Defendants' indefiniteness argument at this time, but Defendants may raise this argument at a later date if appropriate.

B. The '306 Patent Family

1. "administering"

Claim 1 of the '306 patent: "A method for treating a patient who is suffering from excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy, sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia, or nocturnal myoclonus with gamma-hydroxybutyrate (GHB) or a salt thereof, said method comprising:

orally *administering* to the patient in need of treatment at least 5% decrease in an effective dosage amount of the GHB or salt thereof when the patient is receiving a concomitant administration of valproate, an acid, salt, or mixture thereof."[14]

Jazz	Defendants	The Court
No construction necessary	"to give or apply"	No construction necessary

Jazz argues that "administering" requires no construction. (Jazz Open. Br. at 14-16; Jazz Resp. Br. at 13-15). To that end, Jazz submits that "[t]here is nothing in the specification that supports any deviation from the plain and ordinary meaning of 'administering,' let alone to the limited definition Defendants propose: 'to give or apply.'" (Jazz. Open. Br. at 14). Regarding Defendants' proposed construction, Jazz argues that Defendants fail to cite any portion of the DDI patents' specification or prosecution histories to support their definition of "administering." (*Id.*). And Jazz says that the specification "consistently uses the term more broadly than 'to give or apply.'" (*Id.*).

In particular, Jazz points out that the dictionary Defendants cite for their proposed construction "does not even limit the definition of 'administering' to 'to give or apply.'" (*Id.* at 15). Rather, as Jazz notes, that dictionary also defines "administering" to mean "to give out or dispense." (*Id.*). Additionally, Jazz highlights that Defendants "do not dispute that 'administering' carries its plain and ordinary meaning for the '431 patent family." (*Id.*). Jazz suggests that Defendants "clearly have some litigation-driven reason for wanting to construe 'administering' narrowly for the '306 patent family (despite the absence of intrinsic support for such a construction)." (*Id.*). Specifically, Jazz contends that Defendants' motivation is clear: "Defendants advance a theory of divided infringement, claiming that, under their construction, the claims of the '306 patent family in which 'administering' appear will need to be practiced by two

[14] "Administering" also appears in claims 6, 11, 17, 19, 25, 27, 30, and 33 of the '306 patent and claims 1, 13, 20, 27, and 31 of the '302 patent.

separate people—a prescribing physician and a patient." (Jazz Resp. Br. at 13). Finally, Jazz cites other dictionaries that define "administering" more broadly than just "to give or apply." (*Id.*).[15]

Defendants argue that a POSA "would understand 'administering' to conform to the common dictionary definition 'to give or apply' in a medical context." (Def. Open. Br. at 20) (citing Webster's New World College Dictionary 18 (4th ed. 1999)). As Defendants explain, "a [POSA] would understand that the second 'administering' step of claim 11 will be performed by [the] patient that will give or apply the claimed doses, and the first step of claim 11 will be performed by the physician prescribing the drug product." (*Id.* at 21).

Defendants point out that, although their own dictionary does offer another definition for "administering" (i.e., "to give out or dispense'), that definition "is consistent with the very definition Defendants seek . . . ." (Def. Resp. Br. at 12). And regarding Jazz's alternative dictionaries, Defendants assert that "the claim language would not be sensible" with those other definitions. (*Id.*). Defendants identify several cases where the court purportedly construed "administering" consistent with Defendants' proposed definition. (*Id.* at 13-14). Defendants also claim that Jazz has "failed to show that Defendants' construction is inconsistent with the specification, and failed to provide evidence that justifies a construction broader than that proposed by Defendants." (*Id.* at 14-15).

The Court agrees with Jazz that "administering" requires no construction. Federal Circuit law is clear that a "patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope." *Thorner*, 669 F.3d at 1367. Here, Defendants concede that the patentee did not define

[15] (D.E. No. 323-1, Ex. 6, Clinical Trials Dictionary (defining "administering" as "1. To manage or supervise execution, use, or conduct of. 2. To dispense or to give, as with a treatment"); *id.*, Ex. 7, Cambridge International Dictionary of English (defining "administer" as "to cause someone to receive (something)"); *id.*, Ex. 8, Random House Dictionary of the English Language (2nd ed.) (providing multiple definitions for "administer")).

"administering" in the '302 and '306 patents. (Def. Open. Br. at 20). And Defendants do not argue that the patentee provided a clear disavowal of the term's scope. (*See, e.g.*, Tr. at 115:25-116:1). Rather, Defendants maintain that a POSA "would understand 'administering' to conform to the common dictionary definition 'to give or apply' in a medical context." (Def. Open Br. at 20). Defendants, however, have provided insufficient evidence to restrict the scope of "administering" as that term is used in the claims. *See Wasica Finance GmbH v. Continental Automotive Sys, Inc.*, 853 F.3d 1272, 1281-82 (Fed. Cir. 2017) ("It is axiomatic that we will not narrow a claim term beyond its plain and ordinary meaning unless there is support for the limitation in the words of the claim, the specification, or the prosecution history."); *see also Prometheus Labs. Inc. v. Roxane Labs., Inc.*, No. 11-0230, 2013 WL 5333033, at *4 (D.N.J. Sept. 23, 2013) (declining to construe "administering" because the "claim language, as well as the patent specification, say nothing to cause this Court [to] deviate from the ordinary meaning of 'administering'").

Furthermore, Defendants' proposed construction appears to be inconsistent with the specification. For example, the following excerpt from the '302 patent specification uses "administering" more broadly than Defendants' proposed construction:

> In another embodiment, the invention is a method of safely ***administering*** a GHB salt for excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy, sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia, and nocturnal myoclonus in a human patient, comprising: determining if the patient has taken, or will take a concomitant dose of diclofenac; orally ***administering*** an increased amount of a GHB salt to the patient so as to compensate for the effects pf diclofenac on the GHB salt when concomitantly administered.

'302 patent at col. 2, l. 53-62. In that excerpt, the first step of "a method of safely administering a GHB salt" is "determining if the patient has taken, or will take a concomitant dose of diclofenac." (*Id.* at col. 2, l. 53-57). In that context, "administering" is being used more broadly than just "to give or apply"; it is being used to describe a multiple-step method.

Accordingly, the Court concludes that "administering" requires no construction.

2. "currently taking"

Claim 1 of the '302 patent: "A method for the treatment of cataplexy in narcolepsy or excessive daytime sleepiness in narcolepsy in a patient who is *currently taking* gamma-hydroxybutyrate (GHB) or a salt thereof comprising:

> Administering to the patient a dose of divalproex sodium concomitant to a dose of GHB or salt thereof; and
>
> Reducing the daily dosage amount of GHB or salt thereof administered to the patient by at least 20% wherein the daily dosage amount of GHB or salt thereof in the absence of concomitant administration of divalproex sodium is between 4.5 g to 9 g."[16]

Jazz	Defendants	The Court
No construction necessary	"taking within the time period during which the effects of a dose of a drug are still operative in the patient"[17]	No construction necessary

Jazz argues that "currently taking" requires no construction. (Jazz Open. Br. at 18-19; Jazz Resp. Br. at 17-18). Instead, Jazz maintains that "the term means just what it says—that the patient is currently taking the drug specified." (Jazz Open. Br. at 18). Regarding Defendants' proposed construction, Jazz argues that Defendants conflate "currently taking" with the agreed-upon construction of "concomitant."[18] (*Id.*). Defendants' conflation is improper, Jazz says, because "concomitant" requires active administration of a drug, whereas "currently taking" does not. (Jazz Resp. Br. at 18). To that end, Jazz says there "is no basis to read a requirement for active

[16] "Currently taking" also appears in claims 8, 13, 20, 21, 22, 26, 27, and 31 of the '302 patent.

[17] This is a revised proposed construction that Defendants advanced at the *Markman* hearing. (*See* Tr. at 126:4-7). Defendants represented that they proposed this construction to Jazz during the meet-and-confer process prior to the *Markman* hearing. (*Id.* at 125:21-126:1). When the Court asked Defendants which construction they prefer, Defendants responded that each of their proposed constructions is appropriate, but they prefer the revised proposed construction. (*See id.* at 132:11-24).

[18] The parties agree that "concomitant" means "[t]he administration of at least two drugs to a patient either subsequently, simultaneously, or consequently within a time period during with the effects of the first administered drug are still operative in the patient." (Am. Joint Stmt. at 4); *see also, e.g.*,'302 patent at col. 8, l. 37-41.

administration of the drug into 'currently taking,' as the claims require administration at other steps." (*Id.*).

Defendants, on the other hand, argue that "currently taking" does require active administration. (*See* Def. Open. Br. at 24-25; Def. Resp. Br. at 17-19). According to Defendants, the DDI patents' specifications state "that the alleged invention relates to methods of safely administering GHB with MCTs, including valproate . . . ." (Def. Open. Br. at 24). Defendants explain that "the purported reason for any reduction in the dose of GHB is driven by the effects of divalproex sodium in a patient, which would not make sense if 'currently taking' refers, for example, to patients in whom the effects of valproate are no longer operative." (*Id.*). In other words, "[a]ny effects of valproate in a patient (e.g., additive effects, drug/drug interactions) are present, if at all, only when a patient is 'currently taking' valproate such that valproate is still operative in the patient." (*Id.*).

Defendants accuse Jazz of "gloss[ing] over latent ambiguities in the term 'currently taking.'" (*Id.* at 25). Defendants suggest that "'currently taking' can conceivably encompass methods where a patient has previously been administered a dose of divalproex sodium that is no longer operative in that patient, e.g., due to a sufficient lapse of time." Defendants argue that "[s]uch an understanding of the term 'currently taking' would render the claim terms nonsensical, unravelling each claims [sic] requirement to reduce the dosage amount of GHB proportionate to the amount of GHB appropriate 'in the absence of concurrent administration of divalproex sodium.'" (*Id.*).

The Court agrees with Jazz that "currently taking" requires no construction. This term is another common, non-technical term that a POSA would understand in light of the intrinsic evidence. The Court recognizes Defendants' argument that "currently taking" must incorporate

an operability component to comport with the purpose of the DDI patents. But Defendants' proposed construction "invites a violation of [Federal Circuit] precedent counseling against importing limitations into the claims." *Phillips*, 415 F.3d at 1320.

The Court also recognizes Defendants' argument that "currently taking" can encompass scenarios where a patient has taken a drug but, due to the passage of time (or some other factor), the drug is no longer operative in the patient. This argument is unavailing, however, because Jazz is entitled to the full scope of the claim term's ordinary meaning. *See Thorner*, 669 F.3d at 1367 ("The patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope."). Equally unavailing is Defendants' argument that "currently taking" can encompass a scenario where a patient has a prescription filled but has not taken the drug. (*See, e.g.*, Tr. at 140:19-23) ("If someone was provided an asthma drug and had an inhaler but maybe never needed it. The doctor says are you currently taking your asthma drug. Maybe you got the prescription filled but you never needed it."). In the Court's view, a POSA would not consider that patient to be "currently taking" the drug because the patient has not taken the drug.

Accordingly, the Court concludes that "currently taking" requires no construction.

IV. Conclusion

For the reasons set forth above, the Court concludes that all disputed terms except "third container means" require no construction. The term "third container means" is indefinite under § 112, ¶ 2, and the claims reciting that term (claims 17 and 18 in the '650 patent and claim 16 in the '619 patent) are invalid. An appropriate Order accompanies this Opinion.

s/Esther Salas
Esther Salas, U.S.D.J.